

“Every Day, thinking of Deployed Soldiers”





U.S. Army Medical Materiel Development Activity (USAMMDA)

COL Russell E. Coleman, Commander

LTC Karen M. Kopydlowski, Deputy Commander



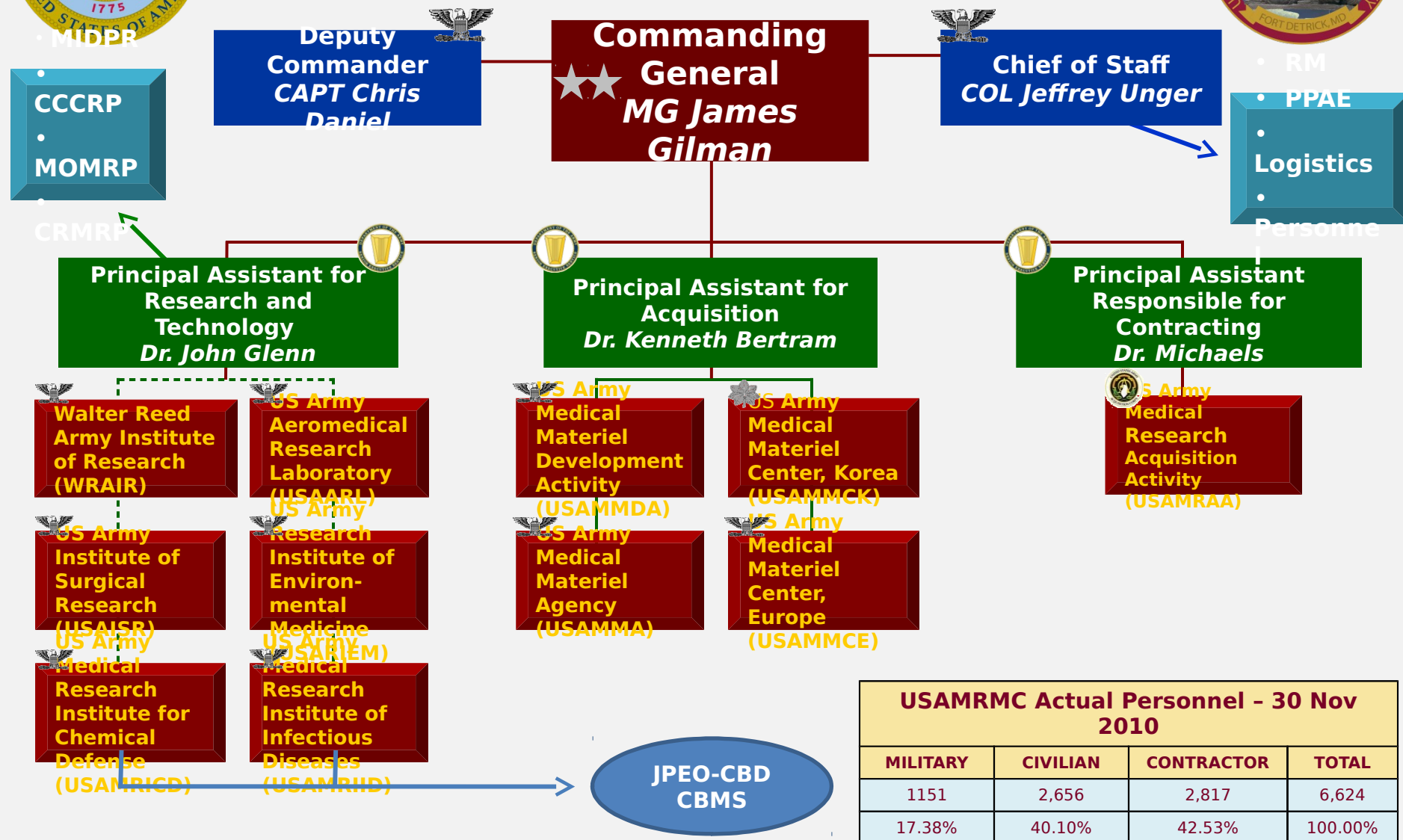
Mission & Vision

Mission . . . *to develop and field medical materiel to protect and sustain our deployed Warfighters*

Vision . . . *to integrate with USAMRMC, Federal agencies, commercial partners and the DoD, as a part of the joint biomedical research and materiel community, to focus on delivering the best medical solutions for today and tomorrow*

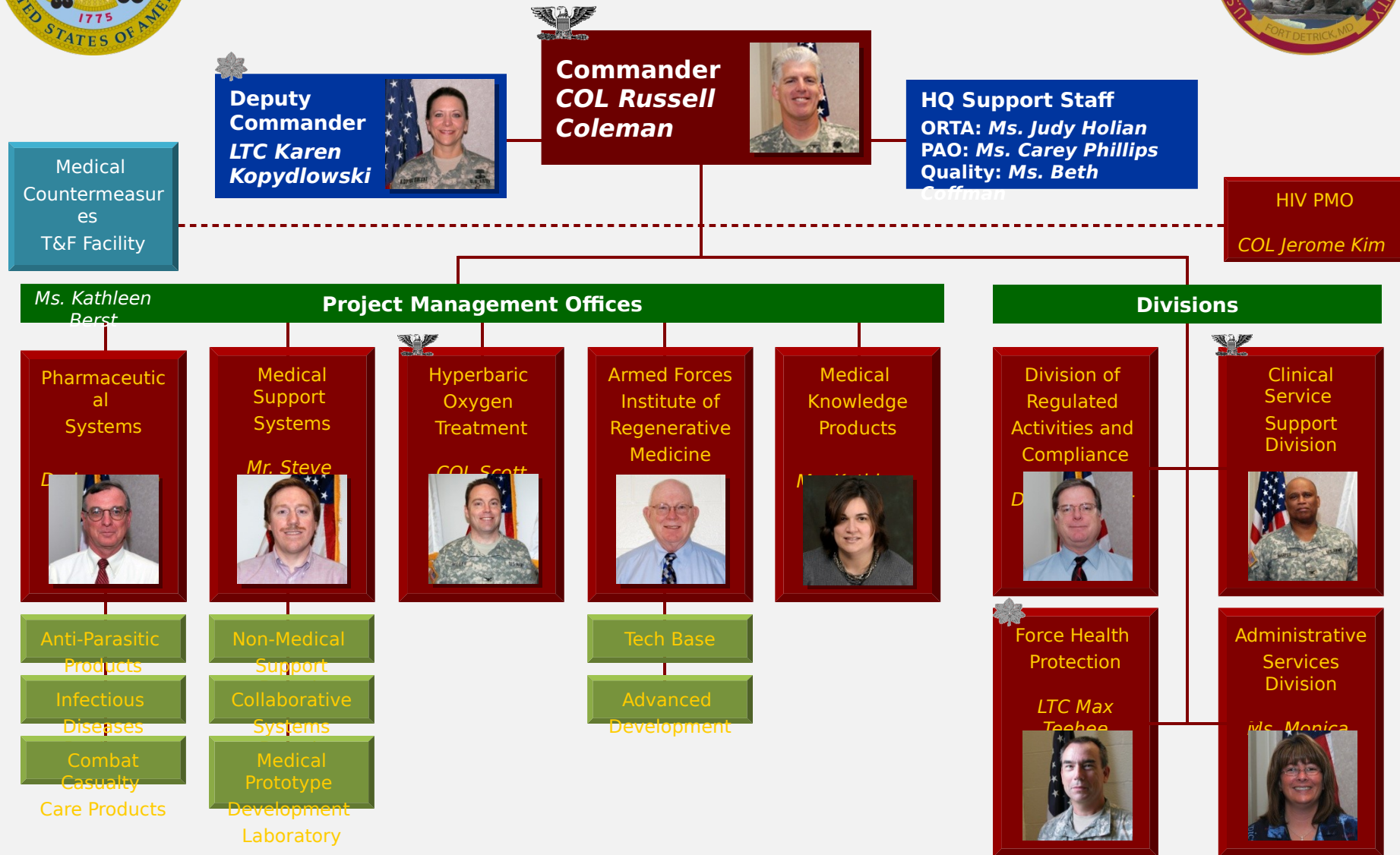


MRMC Organization





USAMMDA Organization



Major Partnerships & Collaborations





Pharmaceutical Systems PMO

Dr. Lawrence K. Lightner, Project Manager
Mr. Scott Doughty, Deputy Project Manager

Mission

Responsible for advanced development of pharmaceutical products for use by the U.S. Military

- Pharmaceutical products

include:

- Drugs
- Vaccines
- Diagnostics
- Blood Products



Medical Support Systems PMO

Mr. Steve Hawbecker, Project Manager
TBD, Deputy Project Manager

Mission

Manage products, medical equipment sets, and activities associated with the acquisition of non-medical materiel solutions that enhance medical readiness in support of Medical Evacuation and Combat Support Hospital requirements for the Warfighter

- 40 products, 24 medical equipment sets, and kits help evacuate and treat common causes of battlefield deaths
- Vehicle programs provide medical evacuation and treatment with a focus on medical mission packages
- Shelter programs provide forward-deployed healthcare providers with operating room shelters and patient care wards
- Activities include: analyzing functional requirements, coordinating with other Program Offices, and providing logistics support and lifecycle management



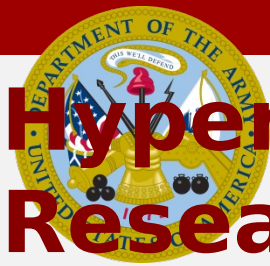
Armed Forces Institute of Regenerative Medicine (AFIRM)

Mr. Terry Irgens, Project Manager
LTC Brian Moore, Deputy Project Manager

Mission

Develop new products and therapies to heal & reset our warriors who have suffered catastrophic traumatic

- New Project Management ~~injuries~~ *Established 2010*
- Multi-institutional: DoD and two Consortia
 - Rutgers - Cleveland Clinic Consortium
 - Wake Forest - Pittsburgh Consortium
 - Institute of Surgical Research, Fort Sam Houston, Texas
- Interdisciplinary network of scientists, focused on 5 key areas
 - Burn Repair
 - Craniofacial Reconstruction
 - Limb and Digit Salvage
 - Scarless Wound Healing
 - Compartment Syndrome



Hyperbaric Oxygen (HBO2) Research PMO

COL Scott Miller, Project Manager
TBD, Deputy Project Manager

Mission

Evaluate the benefit of hyperbaric oxygen in the treatment of chronic symptoms of mild traumatic brain injury (TBI) or post-concussion syndrome

- New Project Management Office – *Established 2010*
- HBO2: Administration of oxygen in a chamber at greater than atmospheric pressure, resulting in higher than normal amounts of oxygen delivered to body tissues
- Anecdotal evidence suggests HBO2 may be beneficial in treatment of acute and chronic symptoms associated with TBI
- Well controlled clinical trials needed to demonstrate HBO2 is effective



Division of Regulated Activities and Compliance (DRAC)

Dr. Robert E. Miller, Director
LTC David Shoemaker, Deputy Director

Mission

Provide full-service regulatory support for products through the DoD acquisition spectrum, from individual investigator-initiated clinical studies to products in the advanced development pipeline

- Serves as Department of the Army Office of The Surgeon General (OTSG) Sponsor
- Primary point-of-contact with all formal and informal communications with the U.S. FDA
- Develops and executes regulatory strategies for compliant use and FDA approval of OTSG-sponsored drugs, vaccines and devices
- Supports researchers and laboratories throughout the Army



Clinical Service Support Division

COL Isiah Harper, Director
TBD, Deputy Director

Mission

Provides clinical support services for the development and advancement of medical products, in the following areas:

- Investigational New Drug (IND) product manufacturing, testing and accountability
- Clinical study monitoring
- Clinical Data Management
- Biostatistical support, including study design and data analysis
- Adverse event monitoring and reporting



Force Health Protection Division

LTC Max Teehee, Director

CPT Ray Casteline, Deputy Director

Mission

Provides for the medical use of the best available Investigational New Drug (IND) countermeasures and prophylaxis for Biological events and endemic disease threats, when there is no FDA approved drugs, in support of the Nation's Warfighters throughout the world

- Established by Executive Order 13139 - Administration of IND to Members of the Armed Forces
- Only given to individuals who volunteer and who sign an Informed Consent document
- Pre-positioned strategic stockpiles
- Specialized MEDCOM Response Capabilities - IND Team (SMRC-IND)



Acquisition

What does USAMMDA purchase?

- Commercial Goods/Services – FY10 = \$23.2M
 - Administrative Materials and Supplies
 - Administrative/Budgetary Support Services
 - Professional, Scientific and Technical Consulting Services
- Research and Development – FY10 = \$92.8M
 - Clinical Trials and Support Activities
 - Developmental and Operational Testing
 - Investigational Product Testing, Storage, and Shipping
 - Manufacturing



Acquisition

How does USAMMDA procure goods and services?

- Commercial Goods/Services
 - Credit Card
 - New and Established Contract Vehicles
- Research and Development Services
 - New and Established Contract Vehicles
 - Grants and Cooperative Agreements
 - Cooperative Research and Development Agreements (CRDA)
 - Interagency Agreements

USAMRAA is the primary contracting office used by



Conclusion

“Every Day, thinking of Deployed Soldiers”

“Every Day, developing Products for Deployed Soldiers”

“Every Day, doing your part for Deployed Soldiers”

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